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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,880	05/25/2005	Jens Peter Gotze	271212000200	6327

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EXAMINER	
FOSTER, CHRISTINE E	
ART UNIT	**PAPER NUMBER**
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,880	GOTZE ET AL.	
	Examiner	Art Unit	
	Christine Foster	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10, drawn to a method for determining the concentration of a BNP precursor.

Group II, claim(s) 11-13, 15-16, 18-19, and 21, drawn to methods of predicting or diagnosing cardiac disease or dysfunction.

Group III, claim(s) 14 and 20, drawn to a method to distinguish between pulmonary and cardiovascular causes of dyspnea.

Group IV, claim(s) 17, drawn to a method for evaluating the effect of coronary angiography.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The technical feature of Group I is the claimed method in which a sample from a mammal is treated with an agent that cleaves a BNP precursor and exposed to an antibody that specifically binds the cleaved product.

Rehfeld et al. ("Processing-independent analysis (PIA)--a new diagnostic tool" Scand J Clin Lab Invest Suppl. 1991;204:9-16) teach a diagnostic tool for accurately measuring secretory

proteins, peptides and their precursors (the abstract and page 10, right column, the last paragraph).

The PIA technique involves preincubating a sample to be assayed with an agent that cleaves the precursor ("proprotein"), which may be trypsin or another endopeptidase (page 11, left column; and Figure 1 and legend). The "processing-independent" peptide is then quantitated by adding an antibody specific for a selected sequence that is present in precursor, intermediates, and in the active mature products (Figure 1 and legend).

Rehfeld et al. demonstrated the feasibility of PIA using gastrin as a model system, but emphasize that the technique is widely applicable to other hormones and proteins (page 14, the last paragraph to page 15, left column).

The teachings of Rehfeld et al. differ from the technical feature at issue in that the reference fails to specifically teach that the PIA technique may be applied to the model system of BNP.

Mischak et al. (US 6,124,430) teach that BNP also undergoes post-translational processing via proteolytic cleavage to generate a mature bioactive peptide, the 32-residue peptide hBNP (see the abstract and column 1). Elevated plasma hBNP is believed to provide a valuable predictive marker of heart disease (column 1).

Therefore, it would have been obvious to one of ordinary skill in the art to employ the PIA technique of Rehfeld et al. in order to accurately measure BNP peptides and precursors. In particular, it would have been obvious to select the BNP system because it fulfills the three criteria for analysis via PIA listed by Rehfeld et al. on page 11; namely, (1) well known gene and precursor structure; (2) well known post-translational processing pathway; and (3) involvement

in disease. One would be motivated to apply the PIA technique for quantitating BNP peptides because BNP is recognized as a biomarker of heart disease.

Therefore, the technical feature linking the inventions of Groups I-IV does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Accordingly, Groups I-IV are not linked by the same or a corresponding special technical feature so as to form a single general inventive concept.

Election of Species

In the event that Group II is elected, the following species election is also required.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Cardiac disease or dysfunction (elect one of the following):

a. Congestive heart failure (see claim 12)

b. Impaired function of the left ventricle (see claim 12)

c. Cardiac failure after myocardial infarction (see claim 12)

d. Arrhythmogenic right ventricular dysplasia (see claim 12)

e. Chronic respiratory disease due to tuberculosis (see claim 12)

f. Congenital heart disease (see claim 12)

g. Obstructive hypertrophic cardiomyopathy (see claim 12)

h. Mortality in elderly (see claim 12)

i. Cardiac-related acute dyspnea (see claim 12)

j. Cardiac transplant rejection episode (see claim 13)

k. Ischemic heart disease (see claim 15)

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above as indicated. The following claim(s) are generic: claim 11. Claims 12-13, 15-16, 18-19, and 21 are subject to species election.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each disease/dysfunction represents a distinct pathological condition that differs in etiology, course of disease, and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Furthermore, the technical feature linking the species (the BNP system in relation to the various disease conditions) does not represent a contribution over the prior art because Mischak et al. teach that BNP is a marker of heart disease.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 8:30-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached at (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1641

LONG V. LE 09/14/07
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